IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	)	
	)	
FOSTER et al.	)	Examiner: J. Graser
	)	
Serial No. : 08/293,728	)	Art Unit: 1641
	)	
Filed: August 22, 1994	)	
	)	
For: S. AUREUS FIBRINOGEN BINDING PROTEIN GENE	)	

DECLARATION UNDER 37 C.F.R. §§ 1.131 and 1.132

I, Dr. Joseph M. Patti, Ph.D., declare and state as follows:

1. I am currently the Vice President of Preclinical Development of Inhibitex, Inc., a licensee of the above-identified application, and a company that specializes in the field of products for human and animal health care based on microbial surface proteins, such as the fibrinogen binding protein that is the subject of the present application. I have also authored or co-authored numerous articles in the field of the present application, and I am the co-inventor of U.S. Patent No. 5,851,744 relating to a collagen binding protein.

2. Prior to my association with Inhibitex, a company which I co-founded in 1994, I worked at the Institute of Biosciences and Technology, Texas A&M University, at the Texas Medical Center, specializing in research regarding the molecular characterization of the collagen and fibronectin-binding proteins. I was also was an assistant professor for four years at the Texas Medical Center. Prior to my association with Texas A&M, I received a B.S. degree in microbiology from the University of Pittsburgh, an MSPH degree from the University of Miami School of Medicine, and a Ph.D. in

biochemistry from the University of Alabama at Birmingham. I am also currently an adjunct assistant professor in this field at Georgia State University. I am thus well familiar with the subject matter of the present invention.

3. In addition, I previously worked very closely with Drs. McDevitt and Foster, the two named inventors of the present invention, and I am well familiar with the facts and circumstances surrounding the conception and reduction to practice in the United States of the invention claimed in the above-identified application. I am also quite familiar with the nature and origins of the journal articles and other publications concerning this invention, including the two publications recently cited by the Examiner in the Official Action dated December 10, 1998 in the above case. In short, as set forth in more detail below, neither of these two publications should be cited as prior art against the present application because (a) they both reflect the work of the inventors of the present application; and (b) I am personally aware that the invention as presently claimed was reduced to practice in the United States prior to the dates of these two publications.

4. With regard to the first of the two publications cited by the Examiner, McDevitt et al., Molecular Microbiology 11(2):237-248 (January 1994), I am quite familiar with the origins and circumstances of this article, and it indeed reflects the present inventors' own work. Although the article has four named authors,

namely Dr. McDevitt, Dr. Foster, Pierre Francois and Pierre Vaudaux, it is in fact the case that this article refers to the work performed by Drs. McDevitt and Foster, the two named inventors of the present application, which was conducted at their labs in Trinity College in Dublin. On the other hand, Messrs. Francois and Vaudaux were individuals working out of laboratories in Geneva, Switzerland who were contacted by Drs. McDevitt and Foster simply to test the materials that had been originated and produced by them at Trinity College, namely the clones containing the DNA molecules coding for an S. aureus fibrinogen binding protein. Because they had carried out some of the testing at the request of Dr. Foster and Dr. McDevitt, some of which was reflected in the Molecular Microbiology article, Messrs. Francois and Vaudaux were included as authors of the article. Accordingly, since these individuals did not contribute to the inventorship of the invention claimed in the present application, they were not included as inventors.

5. It is thus the case that the Molecular Microbiology article cited by the Examiner refers to the present inventors' own work and is thus not prior art to the present application.

6. I am also familiar with the facts and circumstances surrounding the submission and publication of the DNA sequence in the EMBL55 database cited by the Examiner, and this publication also reflects the work of the inventive entity of the present application. As the Examiner recognized, the sequence in question

was submitted confidentially on November 26, 1992, and was not made publicly available until August 27, 1993. The reason that this submission was not publicly available until August 27, 1993 despite being submitted in November, 1992 is that the EMBL55 submissions allow for the submitter to maintain the submitted sequence as confidential until such time as the submitter requests the information be made public (in this case, August 27, 1993). Accordingly, as the Examiner recognized, the effective date of this reference is August 27, 1993, the date that the reference became publicly available.

7. As indicated in the copy of the sequence printout regarding this submission that was attached to the Official Action dated December 10, 1998, the sequence information was provided by Dr. McDevitt, one of the two inventors of the present application. However, this sequence information in fact reflects the work of both Dr. McDevitt and Dr. Foster, the inventive entity of the present application, and thus once again this publication simply describes the inventors' own work and not the prior invention of others. Although the sequence information printout cited by the Examiner only refers to Dr. McDevitt, it is in fact the case that this type of sequence information will typically only be submitted by one inventor, and will thus not reflect the contribution of other authors as would a journal article. It is for this reason alone that Dr. McDevitt submitted the sequence information under his own name and did not include Dr. Foster, and thus the sequence

information regarding the fibrinogen binding protein which constitutes the heart of the present invention was actually invented jointly by Drs. McDevitt and Foster.

8. Accordingly, the EMBL55 database sequence cited by the Examiner, which did not become publicly available until August 27, 1993, less than a year before the filing date of the present application, also reflects the present inventors' own work and not the prior invention of others.

9. Finally, it is in fact the case that the invention claimed in the present application was actually reduced to practice in the United States prior to the effective dates of both of the McDevitt references cited by the Examiner (August 27, 1993 and January, 1994, respectively). In particular, prior to August, 1993, I actually received in the United States a copy of a manuscript which contained the sequence information of the present invention which was sent to me by the inventors for my review. In addition, I also received in the U.S. samples of the actual clones containing the claimed DNA prior to August, 1993 as well. I am thus personally aware that the invention was reduced to practice at this time because of my close work with the inventors throughout the development of the invention. I specifically recall receiving the manuscript containing the claimed sequence while I was working on S. aureus binding proteins at the Texas Medical Center of Texas A&M University prior to August, 1993, and that it was forwarded to me

by Dr. McDevitt and included a handwritten note from him. I believe that any of the correspondence from this time period would be located in files at Texas A&M, and thus although I have thoroughly reviewed my files at my current offices of Inhibitex (near Atlanta, Georgia), I have been unable to locate copies of any of the correspondence reflecting these communications.

I hereby state that all statements made herein based on my own personal knowledge are true and correct and that all statements based on my information and belief are true and correct to the best of my knowledge, and further that all of these statements have been made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

4/9/99
Date

Joseph M. Patti
Dr. Joseph M. Patti, Ph.D.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent

In re patent application of: FOSTER et al.

Serial No.: New U.S. Application
(Divisional of USSN 09/421,868)

Examiner: Graser

Filed: Herewith

Art Unit: 1641

For: S. AUREUS FIBRINOGEN BINDING PROTEIN

Docket No.:
P06282US02/BAS

PRELIMINARY AMENDMENT

COPY

Honorable Assistant Commissioner of Patents
Washington, D.C.

S I R:

Prior to examination, please amend the above-identified application as follows.

IN THE SPECIFICATION:

Page 1, prior to the first line, please insert:

--This is a Divisional of Application No. 09/421,868, filed October 19, 1999, which was a divisional application of Application No. 08/293,728, filed August 22, 1994, now U.S. Patent No. 6,008,341.--

Page 4, line 5, after "in Figure 2" insert --and Sequence ID No. 1--;

line 20, after "Figure 2" insert --and Sequence ID No. 1--.

Page 5, lines 27-33, please delete entirely;

line 35, delete "Figure 5" and insert --Figure 4--.

Page 6, line 4, delete "Figure 6" and insert --Figure 5--;

line 19, delete "Figure 7" and insert --Figure 6--;

lines 33-39, please delete entirely.

Page 7, lines 1-3, please delete entirely;

line 5, delete "Figure 10" and insert --Figure 7--;

line 13, delete "Figure 11" and insert --Figures 8A-B--;

line 21, delete "Figure 12" and insert --Figures 9A-B--.

Page 8, line 32, after "at the", please insert --NCIMB, Aberdeen, Scotland--.

line 33, after "on", please insert --July 2, 1998--.

line 33, after "Accession No.", please insert --NCIMB40959--.

Page 9, line 22, after "KpnI fragment", please insert --which is contained in plasmid pCF10 which was deposited at the National Collections of Industrial and Marine Bacteria, Ltd., Aberdeen, Scotland, in September, 1994, and which was accorded Accession No. 40674--.

line 26, after "Figure 2A" insert --and Sequence ID No. 1--;

line 28, after "97,058 Da" insert --, see Sequence ID Nos. 1 and 2--;

line 30, after "2B" insert --and Sequence ID No. 2--.

Page 10, line 21, delete "(Figure 4, lane 1)";

lines 28-29, delete "(Figure 4, lanes 2 and 3)".

Page 11, line 19, delete "(Figure 5)" and insert --(Figure 4)--;

line 21, delete "(Figure 5)" and insert --(Figure 4)--;

line 23, delete "(Figure 5)" and insert --(Figure 4)--;

line 31, delete "Figure 6)" and insert --Figure 5)--;

line 35, delete "(Figure 6)" and insert --(Figure 5)--;

line 37, delete "Figure 6") and insert --Figure 6)--;

line 39, delete "(Figure 7A)" and insert --(Figure 6)--.

Page 12, line 2, delete "(Figure 6)" and insert --(Figure 5)--;

line 5, delete "(Figure 7A)" and insert --(Figure 6)--;

line 7, delete "and Figure 7A)" and insert --and Figure 6)--;

line 9, after "(SDSDSDSDSDSDGGGC" insert --, Sequence ID No. 16)--;

line 30, delete "(Figure 6)" and insert --(Figure 5)--;

line 34, delete "(Figure 6)" and insert --(Figure 5)--;

line 38, delete "(Figure 7B)" and insert --(Figure 6)--.

Page 13, line 37, delete "(Figure 5)" and insert --(Figure 4)--.

Page 14, line 7, delete "(Figure 8, lane 2)";

line 10, delete "(Figure 8, lane 3)";

line 17, delete "(Figure 8, lane 4)".

Page 15, line 17, delete "(Figure 9)";

line 36, delete "(Figure 10)" and insert --(Figure 7)--;

line 38, delete "(Figure 10)" and insert --(Figure 7)--.

Page 16, line 10, delete "(Figure 11)" and insert --(Figures 8A-B)--;

lines 14-15, delete "(Figure 12)" and insert --(Figures 9A-B)--.

Page 19, line 8, after "VGTLIGFGLL" insert --, Sequence ID No. 17--;

line 9, after "GKIIGID" insert --, Sequence ID No. 18--

line 10, after "MNQTSNETTFNDTNTV" insert --, Sequence ID No. 19--;

line 11, after "AVAADAPAAGTDITNQLT" insert --, Sequence ID No. 20--.

After page 26, please insert the attached sequence listing originally filed August 24, 1998 in Application No. 08/293,728, the grandparent to the present application.

REMARKS

The above changes of the type that were previously made in the parent cases to the present application in order to overcome various objections.

In addition, pursuant to MPEP 2422.05, Applicants are filing herewith a letter requesting transfer of the previously filed sequence information, and are filing the present amendment to insert that sequence listing in the present application. As indicated in the attached letter, the paper copy of the sequence listing attached hereto is identical to the CRF of the grandparent case.

COPY

Favorable consideration of the amended application is respectfully requested.

Respectfully submitted,

Date: 10/5/00

By: _____
B. Aaron Schulman
Registration No. 31,877

LARSON & TAYLOR, PLC
Transpotomac Plaza
1199 North Fairfax Street, Suite 900
Alexandria, Virginia 22314
(703) 739-4900

STATEMENT CONCERNING DEPOSIT OF BIOLOGICAL MATERIAL		
	Application #	09/679,643
	Confirmation #	8447
	Filing Date	05 October 2000
	First Inventor	FOSTER
	Art Unit	1645
	Examiner	Graser, Jennifer E.
	Docket #	P06282US02/BAS

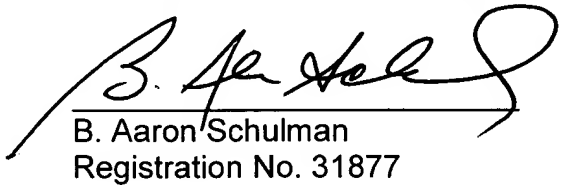
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

S I R:

In response to the Office Action dated November 16, 2004, Applicants submit the following statement.

I am an attorney of record in the above-identified application, and I hereby state that the deposits referred to in the claims and in the amended specification are deposits that have been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application, and that the deposit will be replaced if viable samples cannot be dispensed by the depository.

Respectfully submitted,
STITES & HARBISON, PLLC



B. Aaron Schulman
Registration No. 31877

May 16, 2005

1199 North Fairfax Street, Suite 900
Alexandria, Virginia 22314
(703) 739-4900

SYNOPSIS OF APPLICATION OF WRITTEN DESCRIPTION GUIDELINES

Contents

Example 16: Antibodies

Specification: The specification teaches that antigen X has been isolated and is useful for detection of HIV infections. The specification teaches antigen X as purified by gel filtration and provides characterization of the antigen as having a molecular weight of 55 KD. The specification also provides a clear protocol by which antigen X was isolated. The specification contemplates but does not teach in an example antibodies which specifically bind to antigen X and asserts that these antibodies can be used in immunoassays to detect HIV. The general knowledge in the art is such that antibodies are structurally well characterized. It is well known that all mammals produce antibodies and they exist in five isotypes, IgM, IgG, IgD, IgA and IgE. Antibodies contain an effector portion which is the constant region and a variable region that contains the antigen binding sites in the form of complementarity determining regions and the framework regions. The sequences of constant regions as well as the variable regions subgroups (framework regions) from a variety of species are known and published in the art. It is also well known that antibodies can be made against virtually any protein.

Claim: An isolated antibody capable of binding to antigen X.

Analysis:

A review of the full content of the specification indicates that antibodies which bind to antigen X are essential to the operation of the claimed invention. The level of skill and knowledge in the art of antibodies at the time of filing was such that production of antibodies against a well-

characterized antigen was conventional. This is a mature technology where the level of skill is high and advanced.

The claim is directed to any antibody which is capable of binding to antigen X.

A search of the prior art indicates that antigen X is novel and unobvious.

Considering the routine art-recognized method of making antibodies to fully characterized antigens, the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature, one of skill in the art would have recognized that the spectrum of antibodies which bind to antigen X were implicitly disclosed as a result of the isolation of antigen X.

Conclusion: The disclosure meets the requirement under 35 USC 112 first paragraph as providing an adequate written description of the claimed invention.